



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------------|-------------|----------------------|---------------------|------------------|
| 10/033,621 | 12/27/2001 | Peter C. Meltzer | 70207/56,579 | 9295 |
| 21874 | 7590 | 03/21/2006 | EXAMINER | |
| EDWARDS & ANGELL, LLP | | | AULAKH, CHARANJIT | |
| P.O. BOX 55874 | | | ART UNIT | |
| BOSTON, MA 02205 | | | PAPER NUMBER | |

1625

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/033,621 | MELTZER ET AL. | |
| | Examiner | Art Unit | |
| | Charanjit S. Aulakh | 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9-18, 20-31, 33-35, 37, 39-41 and 44-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-18, 20-31, 33-35, 37, 39-41 and 44-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on Dec. 16, 2005, the applicants have canceled claims 42 and 43 and furthermore, have amended claims 1, 9, 30, 31, 44 and 45.
2. Claims 1-7, 9-18, 20-31, 33-35, 37, 39-41 and 44-49 are now pending in the application.

Response to Arguments

3. Applicant's arguments filed on Dec. 16, 2005 have been fully considered but they are not persuasive regarding enablement, some indefiniteness, most of prior art rejections and ODP rejections. In regard to enablement, the examiner does not agree with the applicants arguments that one of ordinary skill in the art can readily determine which conditions can be treated according to methods of the invention. As stated in the previous office actions, there is no teaching either in the specification or prior art that serotonin uptake and/or dopamine uptake inhibitors are either well known to have therapeutic utility in treating every known neurodegenerative disease, psychiatric disease, dopamine dysfunction and cocaine abuse or have been shown to be efficacious in known animal models of every known neurodegenerative disease, psychiatric disease, dopamine dysfunction and cocaine abuse.

In regard to indefiniteness rejections, the applicants have amended claims 1, 9 and 44 to overcome these rejections. However, the examiner does not agree with the applicants arguments that claims 25-28 are clear and definite. The applicants did not address the issue of difference between inhibiting serotonin uptake and inhibiting serotonin transporter? Is not it the same thing? How these transporters are being

Art Unit: 1625

contacted? Can these transporters be isolated and used in in vitro studies? The uptake of monoamines such as serotonin, dopamine or norepinephrine is inhibited and not of the monoamine transporters? The claims 25 should be directed to a method of inhibiting monoamine transporter only and furthermore, in claims 27 and 28, the term ---of a monoamine transporter or of a dopamine transporter--- should be deleted since the monoamine transporters are responsible for uptake of various amines.

In regard to prior art rejections over Meltzer's reference (J. Med. Chem.), the examiner does not agree with the applicants arguments that this reference can not be cited since it is applicant's own work. There are five additional inventors on this publication in addition to three common inventors and therefore, is available as a prior art reference since the invention was known to others. In regard to Zhao' reference, the examiner agrees with the applicants arguments that this reference does not anticipate instant claims 46-49. In regard to WO reference, this reference still anticipates the instant claims when R1 represents –COR3 and R2 represents –OH group in the compounds of formulae I, II and III (see pages 7-8 and claim 1). Similarly, both the U.S. patents still anticipate the instant claims when R1 represents –COR3 and R2 represents OH group in compounds of formulae I, II and III.

The examiner also does not agree with the applicants arguments regarding ODP rejections. The instant claims are encompassed by the broader values of variables R1 and R2 as stated in the last office action.

Conclusion

4. Rejection of claims 30, 31, 33-35, 37 and 39-41 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.
5. Rejection of claims 25-28 under 35 U.S.C. 112, second paragraph is maintained for the reasons of record.
6. All prior art rejections under 35 U.S.C. 102(a), 102(b) and 102(e) are maintained for the reasons of record.
7. The ODP rejections are maintained for the reasons of record.
8. Claims 1-7, 12-17, 2531, 33-35, 37 and 39-41 are objected for containing non-elected subject matter.
9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

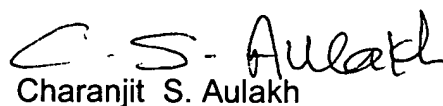
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1625

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charanjit S. Aulakh
Primary Examiner
Art Unit 1625